NON-GMO PROJECT STANDARD

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v16.1

The Non-GMO Project Standard (Version 16.1)
The Non-GMO Project

Version 16.1 of the Non-GMO Project Standard was published and took effect on March 31, 2023. The Non-GMO Project Standard is a normative document under the Product Verification Program. English is the original and official language of this document. In case of any inconsistencies between this document and any translation, default to the official language version.

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1 Introduction

The Non-GMO Project is a nonprofit organization whose mission is to offer rigorous product verification and trustworthy education that empowers people to care for themselves, the planet, and future generations.

In support of our mission, the Non-GMO Project offers a Product Verification Program (PVP) whereby Participants may enroll wholesale goods and retail consumer goods as Products for evaluation against, and determination of compliance with, the Non-GMO Project Standard. The PVP also includes the Non-GMO Project Program Rules and Procedures, the Non-GMO Project Trademark Use Guide, and a written agreement between the Participant and the Non-GMO Project, collectively referred to as Program Documents. Where applicable, a written agreement between the Participant and one or more Technical Administrators (TAs) is also required. If all elements of the PVP are satisfied, including meeting the compliance requirements set forth by the Non-GMO Project Standard, goods may attain Non-GMO Project verification.

To monitor compliance with the PVP, the Non-GMO Project maintains surveillance and auditing programs. The surveillance program routinely tests Verified Products and Inputs and Ingredients to same, for compliance with the Action Thresholds outlined in the Non-GMO Project Standard. The auditing program is in place to ensure that the appropriate supporting documentation associated with Verified Products is on file and fulfills the requirements of the PVP.

Compliance with all Program Documents listed in Table 1-1 is required to attain Non-GMO Project verification.

Table 1-1 Product Verification Program Documents

Product Verification Program Documents: https://www.nongmoproject.org/product-verification-resources/
The Non-GMO Project Standard
The Non-GMO Project Program Rules and Procedures
The Non-GMO Project Trademark Use Guide
The Non-GMO Project Trademark License and Program Participation Agreement

Hereafter, the Non-GMO Project will be referred to as “the Project” and the Non-GMO Project Standard as “the Standard.”

English is the original and official language of the Standard. Terms defined in Appendix A and used in the Standard are capitalized throughout. Requirements listed under headers titled “Global Requirements” apply to the entirety of the section in which they appear (e.g., v16 Section 4.2, Global Chain-of-Custody Requirements, applies to all of v16 Section 4).

1.1 Purpose

The purpose of the Standard is to offer meaning and value to the marketing claim "Non-GMO Project Verified" by creating, maintaining, and keeping publicly available, a set of rigorous requirements against which all Non-GMO Project Verified Products are measured.

1.2 Methodology and Approach

The Project's PVP is based on a practice-oriented and process-oriented Standard that uses both testing and Affidavits as key strategic tools to confirm that practices and processes meet expectations.

Continuous improvement on the part of Participants is required with the common goal of eliminating any Inputs and Ingredients derived from Genetically Modified Organisms (GMOs) from their supply chains.

A Product is a unique branded formula and process, where process could be either the manufacturing or facility process. Product refers to wholesale goods and retail consumer goods that are enrolled in the PVP.

The breadth and depth of Product evaluation is informed by the nature of the Inputs and Ingredients that are represented in, or present in, the Product formulation. Inputs and Ingredients are classified according to three attributes: 1) weight percentage as represented in, or present in, the Product, 2) likelihood that they are derived from a GMO, and 3) whether a testable precursor exists at any point in the supply chain. These three attributes are termed Weight Percentage, Risk Status, and Testability, respectively. Compliance of all Inputs and Ingredients associated with a Product, and whose evaluation is mandatory, is required for verification.

Activities occurring along the chain of custody (CoC) for Products and their Ingredients and Inputs are reviewed for compliance with the segregation, cleanout, traceability, and quality assurance requirements outlined in the Standard. Products must comply, on an ongoing basis, with the labeling requirements outlined in the Standard and cannot carry competing claims or 100% GMO absence claims. Before using the Non-GMO Project verification mark in connection with any Product, Participants will be required to sign a written agreement with the Project.

Although requiring the compliance of all Inputs and Ingredients to Products, the PVP is highly focused on Products, Ingredients, and Inputs that are or are likely to be derived from GMOs. Testable High-Risk Products, Ingredients, and Inputs must comply with the appropriate Action Threshold and Non-Testable High-Risk Products, Ingredients, and Inputs must comply with Affidavit requirements.

Addressing the contamination of seed is a stated priority of the Project. Although traceability back to tested seed is not required for Product verification in general, the Project is actively developing sources of compliant seed as the basis for a sustainable Non-GMO supply chain.

In summary, all Project Verified Products must have systems in place for:

- **Labeling:** Accurate and clear Product labeling
- **Quality assurance:** Maintaining operational consistency and addressing Non-conformities promptly

- **Procurement:** Obtaining Inputs and Ingredients in accordance with uniform and meaningful specifications
- **Testing:** Meaningful, ongoing testing of Major High-Risk Inputs and Ingredients
- **Segregation and Cleanout:** Protecting compliant Inputs and Ingredients from commingling with non-compliant materials
- **Traceability:** Supply chain traceability, especially following Input and Ingredient testing or the establishment of a compliant Affidavit

2 Scope of Product Verification Program

The scope of the Standard and the PVP encompasses the following Product categories, including their Inputs, Ingredients, and associated activities.

2.1 Product Categories

2.1.1 The following types of wholesale or retail goods are eligible for verification:

2.1.1.a Seed and vegetative propagation materials

2.1.1.b Wholesale or retail goods for human or pet use that are either ingested or topically applied

2.1.1.b.i Over-the-counter (OTC) drugs and homeopathic remedies

2.1.1.c Wholesale or retail goods for human or pet use that are not ingested or topically applied

2.1.1.d Livestock, poultry, bee, and seafood feed and supplements

2.1.2 The following types of goods are ineligible for verification:

2.1.2.a Controlled substances under U.S. or Canadian law and all other prohibited Inputs and Ingredients listed under Section 2.2.3

2.1.2.b Certain medicines and other medical goods

2.1.2.c Live animals

2.1.2.d Synthetic pesticides

2.1.2.e Goods composed entirely of Non-Risk Inputs and Ingredients and that are part of a Non-Risk Category

2.1.2.e.i Non-Risk Categories include, but are not limited to, 100% salt goods, unflavored still beverages, unflavored carbonated beverages, and unflavored electrolyte beverages

2.1.2.f Goods making a voluntary or mandatory disclosure under The National Bioengineered Food Disclosure Standard[1]

[1] 7 CFR § 66 (2018).

2.2 Input and Ingredient Evaluation

2.2.1 Mandatory Input and Ingredient categories (categories to Product formulations that must be evaluated and found compliant):

2.2.1.a Seeds and vegetative propagation materials ONLY when the same seeds or vegetative propagation materials are the Products seeking verification.

2.2.1.b All Inputs and Ingredients represented in, or present in, the Product formulation from the following categories must comply with the requirements of the Standard in order for the finished Product to be Verified.

2.2.1.b.i Unprocessed raw agricultural materials such as vegetables, grains, fruit, greens, herbs, other fresh foods, fibers

2.2.1.b.ii Manufacturing Inputs and Ingredients, including flavorings, seasonings, colorings, additives, and all other substances present in final, manufactured Products

2.2.1.b.iii Animal derivatives including dairy, meat, eggs, wool, and hides; derivatives of apiculture including, but not limited to, honey and beeswax; derivatives of seafood

2.2.1.b.iv Processed agricultural Inputs and Ingredients

2.2.1.b.v Packaging that is directly immersed in or combined with liquid for the purpose of making the Product available for human consumption including tea, coffee, spice, and soup bags but not including any part of the packaging other than the bag

2.2.1.b.vi Rations and supplemental feed for livestock, poultry, bees, seafood, and other animals

2.2.1.c Other Inputs and Ingredients used in personal care and cosmetic Products, and textiles

2.2.1.d Dietary supplements, vitamins, and herbal preparations

2.2.1.e Microorganisms, Enzymes, and Growth Media

2.2.1.f Processing Aids present in the finished Product at 0.5% or more

2.2.1.g Processing Aids listed on the Ingredient panel of a retail consumer good, or Input/Ingredient disclosure documentation of a wholesale good

2.2.2 Input and Ingredient categories that are out of the scope of the Standard (categories that do not affect the evaluation of the overall Product formulation, including Weight Percentage, Risk Status, and Testability, do not need to be evaluated and do not need to demonstrate compliance with the Standard.)

2.2.2.a Processing Aids used in the manufacture or processing of a finished

Product, Ingredient, or Input are out of the scope of review if present in the finished Product at less than 0.5% and not declared on the retail Ingredient panel or the Input/Ingredient disclosure documentation of a wholesale Product. For the purposes of the Standard, fermentation Microorganisms are not considered to be Processing Aids. See Section 9.3 for the evaluation of and compliance requirements for Microorganisms.

2.2.2.b Purified carbon dioxide (CO_2) from either biological or non-biological sources

2.2.2.c Fully composted materials and animal manures not sourced from Genetically Modified (GM) animals

2.2.3 Prohibited Inputs and Ingredients:

2.2.3.a Controlled substances under U.S. or Canadian law

2.2.3.b Recombinant bovine growth hormone (rBGH)[2]

2.2.3.c GM animals including those that are cloned, their progeny, and their derivatives

2.2.3.c.i GM Salmon and their derivatives

2.2.3.d Manure sourced from GM animals

2.2.3.e Synthetic Biology,[3] its derivatives, and any organisms, Inputs, or Ingredients, or derivatives thereof, represented as synthetic biology[3] in any public communications[4]

3 Input and Ingredient Classification

Each Input and Ingredient must be classified in accordance with Section 3 and meet all applicable requirements under the Standard to be included in a Verified Product.

3.1 Weight Percentage

All Inputs and Ingredients must be classified according to their Weight Percentage as represented in, or as present in, the finished Product, not counting the weight of salt or added water present in the finished Product. Excluded from the Weight Percentage calculation are: 1) Processing Aids present in the finished Product at less than 0.5% and not declared on the retail Ingredient panel or the Input/Ingredient disclosure documentation of a wholesale Product, and 2) purified CO_2.

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[2] Recombinant bovine growth hormone is also known as recombinant bovine somatotropin (rBST).

[3] The terms "Synthetic Biology" (uppercase and defined in Appendix A) and "synthetic biology" (lowercase) are referenced intentionally here. As there is no universally accepted definition for synthetic biology, the term "synthetic biology" (lowercase) includes usage of that term (and comparable terms) by industry even if such terms are not necessarily in full alignment with the Standard's definition.

[4] Public communications include, but are not limited to, marketing materials, patent filings, SEC filings and other regulatory documents.

For livestock, poultry, bee, and seafood feed other than pet food, the Weight Percentage categories below are calculated based on the weight of the Input as a percentage of the Ration fed to the animal. Rations demonstrating compliance on an as-fed basis have additional reporting requirements per Section 8.3.1.d. Rations demonstrating compliance on a dry-matter basis do not have any additional reporting requirements. Per Section 8, all Minor and Micro Inputs of livestock and poultry Rations are exempt from evaluation.

Unless a Verified-Status Ingredient, the Inputs to each Major or Minor Ingredient must be classified and evaluated back to the point in the supply chain where they can be confirmed compliant with the Standard's requirements. If the TA determines that a Micro Ingredient qualifies for Section 3.1.3.b no further breakdown or classification is required.

3.1.1 **Major Inputs and Ingredients**, each of which represents, or is present as, 5% or more of the finished Product.

3.1.2 **Minor Inputs and Ingredients**, each of which represents, or is present as, at least 0.5% but less than 5% of the finished Product.

3.1.3 **Micro Inputs and Ingredients**, each of which represents, or is present as, less than 0.5% of the finished Product. The depth of evaluation for these Inputs and Ingredients, including application of the limits in Section 3.1.3.a, is limited to the organism from which they were derived, as opposed to Growth Medium or feed. Certain Micro Inputs and Ingredients are eligible for Micro Exemption under Section 3.1.3.b.

3.1.3.a **Inputs and Ingredients ineligible for Micro Exemption**:

3.1.3.a.i **High-Risk Ingredients on the List of Bioengineered Foods.**[5]

3.1.3.a.ii **High-Risk Ingredients not on the List of Bioengineered Foods**[6] for which the Participant has actual knowledge that the Ingredients contain detectable modified genetic material, and said Ingredients retain detectable modified genetic material in the finished Product.

3.1.3.a.iii **Viable Microorganisms** present in the finished Product.

3.1.3.a.iv **Functional Enzymes** present in the finished Product and listed on the retail Ingredient panel, or for Products sold without retail labeling, listed on the Input/Ingredient disclosure documentation.

3.1.3.a.v **High-Risk Micro Ingredients**, other than artificial and natural flavors, Enzymes, and Microorganisms if they are either:

3.1.3.a.v.a) Named in text on the Principal Display Panel (PDP) of a retail consumer Product and the same name or any common names by

[5] 7 CFR § 66.1 (2018); 7 CFR § 66.6 (2018).

[6] 7 CFR § 66.6 (2018).

which the Ingredients are known, are listed on the Ingredient declaration or supplement facts panel

3.1.3.a.v.b) Named in parenthetical Ingredient declarations or supplement facts panels and are reasonably considered to characterize a Major, Minor, or Micro Ingredient that is named on the PDP of a retail consumer Product

See Section 3.2 for an explanation of Risk Status.

3.1.3.b **Ingredients present in Products as Micro Ingredients** and not listed in Section 3.1.3.a, and Inputs represented in Products as Micro Ingredients, may be exempt from further evaluation (Micro-exempted) provided no Product contains more than 0.9% total exempt Micro Ingredients by Weight Percentage.

3.2 Risk Status

All Inputs and Ingredients must be classified according to their Risk Status. Risk Status denotes the likelihood that an Input or Ingredient is or is derived from a GMO. In order to focus the PVP on Inputs and Ingredients at risk for GMO contamination throughout the CoC, the Standard recognizes five Risk Statuses (Table 3-1).

Table 3-1 The Five Risk Statuses

Risk Status	Definition
Verified Status	Products that have been Verified under the PVP at wholesale or retail and are purchased for use as Inputs or Ingredients to different Products enrolled in the PVP
High Risk (see Appendix B)	Organisms and the Inputs and Ingredients derived from them for which GM counterparts are widely commercially available
Monitored Risk (see Appendix C)	Organisms and the Inputs and Ingredients derived from them for which GM counterparts are in the research and development stages, which have been developed but are not widely commercially available, or for which known GM contamination has occurred
Low Risk	Organisms and the Inputs and Ingredients derived from them that are not classified as Monitored Risk or High Risk
Non-Risk	Inputs and Ingredients that are not derived from biological organisms and are not, therefore, susceptible to Genetic Modification

3.3 Testability

Inputs and Ingredients are either Testable or Non-Testable. Testable Inputs and Ingredients have a point in the supply chain where the Input or Ingredient contains sufficient intact

deoxyribonucleic acid (DNA) or protein to return valid molecular or immunological test results, and acceptable molecular tests or immunological tests are publicly commercially available to cover all events for which the Project requires testing. Non-Testable Inputs and Ingredients do not have a point in the supply chain where the Input or Ingredient contains sufficient intact DNA or protein to return valid molecular or immunological test results and/or no acceptable molecular tests or immunological tests are publicly commercially available. Some organisms and their derivatives are both Testable and Non-Testable according to the above criteria.

3.3.1 For Testable High-Risk Inputs and Ingredients (including for use in pet food) other than animal feed, the molecular method polymerase chain reaction (PCR) is the only acceptable testing methodology.

3.3.2 For Testable High-Risk Inputs to animal feed (other than pet food), either the molecular method PCR or immunological methods may be used to demonstrate compliance with the Action Threshold.

3.4 Product Compliance by Input and Ingredient Classification

Full Input and/or Ingredient disclosure is required in most cases for Products. Table 3-2 summarizes the compliance pathways available to Verified-Status, Monitored-Risk, Low-Risk, and Non-Risk Inputs and Ingredients. The compliance pathways of these four Risk Statuses are unaffected by Weight Percentage in the finished Product and Testability. Table 3-3 summarizes the various compliance pathways for Testable and Non-Testable High-Risk Inputs and Ingredients when they are Majors, Minors, and Micros. Table 3-2 and Table 3-3 are summaries; where appropriate, additional compliance requirements, including those outlined in Section 10, Product Specifications and Labeling and Section 11, Quality Assurance, may also apply.

Table 3-2 Compliance of Verified-Status, Monitored-Risk, Low-Risk, and Non-Risk Inputs, Ingredients, and Products

Verified Status
1. Provide proof of Verified Status of appropriate scope. 2. Participant complies with Section 4, Chain of Custody, from the point of procurement to the finished Product.
Monitored Risk
See requirements for Low Risk.
Low Risk
1. Comply with Section 4.3, Segregation. If the facility does not use any High-Risk Inputs or Ingredients, then demonstration of this fact is sufficient to fulfill this requirement. **AND EITHER** a. Provide a complete Input and Ingredient disclosure. **OR** b. Comply with Section 7.5, Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients.
Non-Risk
1. Provide a complete Input and Ingredient disclosure. **OR** 2. Comply with Section 7.6, Non-Risk Major, Minor, and Micro Inputs and Ingredients.
Note: Inputs and Ingredients from the Verified-Status, Monitored-Risk, Low-Risk, and Non-Risk Risk Statuses have the same compliance pathways regardless of Testability or Weight Percentage attributes. For example, Non-Risk Major, Minor, and Micro Inputs and Ingredients have the same compliance pathways.

Table 3-3 Compliance of Testable and Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients

Major	Minor	Micro
Testable High Risk		
1. Submit a complete Input and Ingredient disclosure. 2. Comply with Section 4, Chain of Custody. 3. Comply with Section 5, Onsite Inspections. **AND EITHER** a. Comply with Section 6, Sampling and Testing. **OR** b. Where eligible, comply with Section 7.4, Affidavit Compliance Based on Country of Origin. 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance.	1. Comply as a Major. **OR** 2. Submit a complete Input and Ingredient disclosure. 3. Comply with Section 4, Chain of Custody. 4. Where eligible, comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients. 5. Comply with Section 10, Product Specifications and Labeling. 6. Comply with Section 11, Quality Assurance.	1. Comply as a Major. **OR** 2. Comply as a Minor. **OR** 3. Comply with Section 3.1.3, Micro Inputs and Ingredients. 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance.

Table 3-3 Compliance of Testable and Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients, Continued

Major	Minor	Micro
Non-Testable High Risk		
1. Submit a complete Input and Ingredient disclosure. 2. Comply with Section 4, Chain of Custody. 3. Comply with Section 5, Onsite Inspections. **AND EITHER** a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. **OR** b. Where eligible, comply with Section 7.4, Affidavit Compliance Based on Country of Origin. 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance.	1. Comply as a Major. **OR** 2. Submit a complete Input and Ingredient disclosure. 3. Comply with Section 4, Chain of Custody. **AND EITHER** a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. **OR** b. Where eligible, comply with Section 7.4, Affidavit Compliance Based on Country of Origin. 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance.	1. Comply as a Major. **OR** 2. Comply as a Minor. **OR** 3. Comply with Section 3.1.3, Micro Inputs and Ingredients. 4. Comply with Section 10, Product Specifications and Labeling. 5. Comply with Section 11, Quality Assurance.

4 Chain of Custody

Compliant Products, Ingredients, and Inputs must maintain their integrity while being moved through various activities along the CoC.

4.1 Activities

CoC requirements apply beginning at the point that Non-Risk, Low-Risk, Monitored-Risk or Verified-Status of an Input or Ingredient is confirmed, at the point of testing, or at the point where compliant Affidavits are procured. When relevant to the verification of the Product, the following activities are subject to review and must be found to be compliant with the applicable Standard sections (Table 4-1).

Table 4-1 Activities Along the Chain of Custody

Type of Activity	Comment
Agricultural production—seeds and crops	Includes farm production, harvest, and post-harvest handling and storage on farm or farm-related facilities.
Handling	Includes any form of post-harvest movement, storage, transformation, or labeling of goods along the entire CoC from seed to consumer, except for Products enclosed in final retail packaging.
Storage	Includes all links in the CoC from seed to finished Product.
Distribution	This may or may not involve physical handling of goods.
Processing	Includes all conveyance, storage, processing, handling, assembly, or packaging of goods within any given production facility.
Manufacturing	Involves the production, and combination of, Inputs and Ingredients to make the finished Product.
Packaging and labeling	Includes any and all events during which the packaging or labeling of goods is added, removed, or altered.

4.2 Global Chain of Custody Requirements

4.2.1 All required procedures must be written and accessible to all appropriate staff and updated as necessary.

4.2.2 All appropriate staff working with compliant Inputs, Ingredients, and Products must be adequately trained in the required procedures.

4.2.3 All records must be maintained for a minimum of 3 years.

4.3 Segregation

4.3.1 Systematic procedures must be in place during activities to keep compliant Inputs, Ingredients, work-in-progress, and finished Products separate from all non-compliant High-Risk materials.

4.3.2 Segregation measures are also required for instances where any required testing occurs after the Input or Ingredient in question has entered the facility.

4.4 Cleanout

4.4.1 Receiving, production, processing, manufacturing, transfer, and storage facilities, as well as shipping and transportation conveyances, must be inspected and cleaned/purged as needed to remove sources of GMO contamination, and all relevant cleaning, purging, and inspections must be documented.

4.5 Traceability

4.5.1 Each lot of Verified Product must be traceable back to specific lots of the Inputs and Ingredients used in its production. If lots of compliant Inputs and/or Ingredients are commingled in storage before use in production of a certain lot of Product, the lot numbers related to all commingled lots must be linked to that particular lot of Product.

4.5.2 Testable High-Risk Inputs and Ingredients must be traceable back to the lots that demonstrate compliant test results. Non-Testable High-Risk Inputs and Ingredients must be traceable back to the lots associated with compliant Affidavits.

4.5.3 Systematic procedures must be in place for tracking lot numbers and/or marking and labeling of packaging, containers, and storage facilities to ensure traceability of Inputs, Ingredients, work-in-progress, and finished Products at all points in the production process.

4.5.4 Traceability records must explicitly trace and track the compliance of Inputs, Ingredients, and finished Products.

5 Onsite Inspections

5.1 At minimum, Producing Facilities are required to be inspected annually when Parallel Processing of the same Major High-Risk Input or Ingredient to a Product is occurring.

5.2 Contract processors that are not Participants are exempt from inspection as long as Products, Ingredients, and Inputs they manufacture are the result of a system that has been designed to avoid GMOs. The availability of this exemption will be revisited during the next Standard revision.

5.3 The TA may require additional inspections based on an overall risk analysis of the supply chain undergoing evaluation, regardless of the Weight Percentage, Risk Status, or Testability of Inputs, Ingredients, or Products.

5.4 At the TA's discretion, unannounced inspections may be used to ensure compliance with the Standard, regardless of the Weight Percentage, Risk Status, or Testability of Inputs, Ingredients, or Products.

6 Sampling and Testing

All High-Risk Inputs and Ingredients must comply with the relevant Action Threshold through either Section 6 or Section 7, unless otherwise allowed by a different section of the Standard.

The combination of Weight Percentage, Risk Status, and Testability determines the pathways available for the demonstration of compliance with the relevant Action Threshold. Refer to Table 3-2 and Table 3-3 for summaries of the appropriate compliance pathways.

6.1 Action Thresholds

Absence of all GMOs is the target for all Verified Products. Continuous improvement practices toward achieving this goal must be part of the Participant's quality assurance systems. A key outcome of such quality assurance systems is to meet or continually be below the applicable Action Threshold. Testable High-Risk Inputs and Ingredients that do not comply with the applicable Action Threshold cannot be intentionally used in Verified Products, unless otherwise allowed by a different section of the Standard.

The Non-GMO Project has established the following Action Thresholds for Testable High-Risk Inputs and Ingredients (Table 6-1).

Table 6-1 Action Thresholds

Category	Action Threshold[a]
Seed and vegetative propagation materials	0.25%
Wholesale or retail goods for human or pet use that are either ingested or topically applied including OTC drugs and homeopathic remedies	0.9%
Livestock, poultry, bee, and seafood feed and supplements, including those used for animal-derived Inputs and Ingredients to all Products	5%[b]
Wholesale or retail goods for human or pet use that are not ingested or topically applied including, but not limited to, Inputs and Ingredients to packaging, cleaning supplies, and textiles	1.5%

[a] For all crops not listed in Appendix B.1.1 and Appendix C.1.1, there is no allowable presence.

[b] Compliance with this Action Threshold may be based on the quarterly average of all lots tested.

6.2 Global Sampling Requirements

6.2.1 **A statistically valid sampling and testing plan** must be designed based on a risk assessment of the production and handling system and must reflect the level of monitoring appropriate for the risks inherent in the production and handling system, as well as industry standards.

6.2.1.a The sampling and testing plan must be approved by the TA before any test results acquired on the basis of said sampling and testing plan may be used to demonstrate compliance with the Action Threshold.

6.2.1.b Unless otherwise allowed by a different section of the Standard, compliant sampling and testing must occur at least once post-harvest for all Inputs and Ingredients, depending on contamination risks.

6.2.1.c When achieving statistical validity through crop sampling cannot be done without destroying significant quantities of the consumer good

(e.g., for large crops such as papaya, sweet corn, zucchini and yellow summer squash), the TA may shift testing to the seed level with limited post-harvest spot testing.

6.2.2 Compositing samples

Statistical calculations can also be used to design compositing strategies under which portions of multiple samples can be combined and tested together to reduce the number of tests required.

6.2.2.a Compositing must be done in a manner that ensures that any single sample in excess of the relevant Action Threshold produces a positive result for the composite sample as a whole. If a result is obtained for the composite that indicates that one or more single samples exceeds the relevant Action Threshold, the lot must be rejected, or if sub-lots are segregated and not commingled, then retesting of individual lot samples may be possible to salvage compliant lots.

6.3 Global Testing Requirements

6.3.1 Participants must demonstrate compliance with the applicable Action Threshold.

6.3.2 Compliance must be demonstrated by ensuring that each lot of Testable High-Risk Input or Ingredient is compliant with Section 6 prior to its use in a Verified Product.

6.3.3 The sample Matrix must be appropriate for the testing method to yield valid results. If necessary, the precursor from which the Input or Ingredient was derived must be tested.

6.3.3.a All GM events for which the Project requires testing must be tested for and the results must be conclusive.

6.3.3.b Test results must be traceable back to the lot number(s) of the precursor, Input, or Ingredient.

6.3.3.c From the point of testing forward, the activities associated with the precursor, Input, or Ingredient must comply with Section 4.

6.3.4 Test results must be submitted to the TA for review prior to initial verification.

6.3.5 All test results from the preceding year must be submitted to the TA for review at annual renewal.

6.3.6 In cases where the requirements of Section 6.1 are demonstrated to be problematic to achieve for every lot, compliance may be demonstrated by ensuring that test results for all lots of High-Risk precursor, Input, or Ingredient used during each 6-month period average at or below the relevant Action Threshold, with no single lot of precursor, Input, or Ingredient ever exceeding the relevant Action Threshold by more than a factor of two. The availability of this compliance pathway will be revisited during the next Standard revision.

6.3.6.a Planting seed, vegetative propagation materials, and livestock, poultry, bee, and seafood feed cannot demonstrate compliance via Section 6.3.6.

6.3.6.b The Participant must justify in writing to the TA why the requirements of Section 6.1 are problematic to achieve for every lot at initial verification and at each renewal.

6.3.6.c The Participant is responsible for ongoing monitoring of test results to ensure compliance for each 6-month period.

6.4 Molecular Testing Methods

6.4.1 Testable High-Risk Inputs and Ingredients will be compliant with Section 6.4 if all the following criteria are met:

6.4.1.a Appropriate laboratory controls indicate that the DNA of the precursor, Input, or Ingredient is sufficiently intact to allow valid quantitative analysis by PCR.

6.4.1.b The testing is conducted by an approved laboratory in compliance with Section 6.4.2 and the analysis report references the specific lot of precursor, Input, or Ingredient, where applicable, used by the Participant.

6.4.1.c The analysis report shows that the GM contamination of the precursor, Input, or Ingredient in question is at or below the relevant Action Threshold.

6.4.2 **Laboratories approved** by the Project must carry out testing, except in cases where Inputs and Ingredients are compliant with Section 7.4. Approved laboratories possess a Certificate of Approval detailing the crops for which they are approved to test and are listed on the Project's website.

6.4.3 **Laboratory testing** may employ quantitative, semi-quantitative, or qualitative PCR.

6.4.3.a Quantitative PCR may be used to demonstrate compliance with the Action Threshold if:

6.4.3.a.i For each test panel conducted on a precursor, Input, or Ingredient, the sum of all test results is at or below the relevant Action Threshold.

6.4.3.b Semi-quantitative PCR may be used to demonstrate compliance with the Action Threshold if:

6.4.3.b.i The upper limit of the range in which the result is reported must be at or below the relevant Action threshold.

6.4.3.c Qualitative PCR may be used to demonstrate compliance with the Action Threshold if:

6.4.3.c.i The PCR limit of detection is 0.1% or lower.

6.4.3.c.ii Each test result for each Testable High-Risk precursor, Input, or Ingredient is negative.

6.4.3.c.iii Should any test result be positive for a GM event, the Testable High-Risk precursor, Input, or Ingredient must be tested in compliance with Section 6.4.3.a or Section 6.4.3.b to demonstrate compliance with the Action Threshold. If the Testable High-Risk precursor, Input, or Ingredient cannot be tested in compliance with Section 6.4.3.a or Section 6.4.3.b, compliance with the appropriate Action Threshold cannot be demonstrated and the lot cannot be used in a Verified Product.

6.5 Immunological Testing Methods

6.5.1 Immunological testing methods such as Enzyme-linked Immunosorbent Assay (ELISA) or lateral flow strip tests may be used in lieu of molecular testing methods to demonstrate compliance of animal feed (other than pet food) with the appropriate Action Threshold, when the methods meet the criteria in Section 6.5.

6.5.2 **Analysts must be trained, and their proficiency established** to ensure that they use and interpret the tests reliably and according to the manufacturer's specifications. Participants must document the in-house training and evaluation of performance.

6.5.3 **In cases where immunological testing methods are permissible by the Standard**, they must cover all GM events for which the Project requires testing. If all GM events for which the Project requires testing are not covered, samples must be tested in compliance with Section 6.4.

6.5.3.a Quantitative immunological methods may be used to demonstrate compliance with the Action Threshold when:

6.5.3.a.i The result for each assay counted toward overall contamination is either below the limit of detection or returns a number within the range of quantification and is not above the upper limit of the range of detection.

6.5.3.a.ii The overall contamination of the Testable High-Risk precursor, Input, or Ingredient is indicated by the sum of each test panel or by following the manufacturer's instructions for the interpretation of test panel results.

6.5.3.b Qualitative immunological methods may be used to demonstrate compliance with the Action Threshold when:

6.5.3.b.i Each test result for each GM event per Testable High-Risk precursor, Input, or Ingredient is negative.

6.5.3.b.ii Should any test results be positive, the Testable High-Risk precursor, Input, or Ingredient must be tested according to Section 6.5.3.a, Section 6.4.3.a, or Section 6.4.3.b to demonstrate compliance with the Action Threshold.

7 Affidavits

In most cases, testing is a required validation tool for confirming compliance with the Action Threshold of Testable High-Risk Major Inputs and Ingredients. In the case of Non-Testable High-Risk Inputs and Ingredients, where testing is not an available validation tool, or in the case of Inputs and Ingredients classified as other than Testable High-Risk Major, the Project uses a process-based approach that includes comprehensive Affidavits as an alternate validation tool. In some situations, the frequency and necessity of testing or the need for certain Affidavits may be reduced based on the country in which a crop was grown.

7.1 Global Affidavit Requirements

7.1.1 At minimum, all Affidavits must include the signature and the printed name of the party signing the Affidavit, and the date.

7.1.2 The party signing the Affidavit must have sufficient knowledge of the supply chain to authoritatively sign.

7.1.3 If appropriate, Affidavits should be accompanied by supporting documentation.

7.1.4 At the discretion of the TA or the Project, Affidavits may be required in additional situations not explicitly identified in Section 7.

7.1.5 Unless otherwise stated below, Affidavits must be updated as appropriate to reflect changes to the crops, precursors, Inputs, Ingredients, systems, processes, or operations they reference.

7.2 Non-Testable High-Risk Inputs and Ingredients

7.2.1 Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients are identified in Appendix B.1. An Affidavit stating that any such Non-Testable High-Risk Major, Minor, or Micro Input or Ingredient is Non-GMO is required to establish compliance with Section 7.2. Organisms, precursors, Inputs, or Ingredients identified as Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients in Appendix B.1 that are subject to any European Union (EU) GMO Directives or Regulations,[7] including but not limited to any such items that an EU Member State has determined are subject to such GMO Directives or Regulations, are GMO under the Standard; Non-Testable High-Risk Affidavits accompanying such organisms, precursors, Inputs, or Ingredients do not

[7] See, e.g., without limitation, Council Regulation 1829/2003/EC on genetically modified food and feed; Council Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

establish them as Non-GMO and will not be considered for compliance with Section 7.

For the avoidance of doubt, all Non-Testable High-Risk Major, Minor, and Micro Inputs and Ingredients remain subject to evaluation, and may be deemed GMO, under the Standard, regardless of whether such Inputs or Ingredients are regulated as GMOs (or have been deemed Non-GMO) by any EU GMO Directive or Regulation, or have been deemed subject to any EU GMO Directive or Regulation by a Member State.

7.2.2 The Project has issued a standardized Non-Testable High-Risk Affidavit. This is the only Affidavit compliant with Section 7.2.1.

7.2.3 Unless otherwise allowed by a different section of the Standard, Affidavits for any Non-Testable High-Risk Major, Minor, or Micro Input or Ingredient must be submitted to the TA for review prior to initial verification and, at minimum, updated and resubmitted annually upon each renewal to ensure compliance with Section 7.

7.2.4 Testable High-Risk Major Inputs and Ingredients listed in Appendix B.1 must be compliant with Section 6 or Section 7.4. Testable and Non-Testable High-Risk Inputs and Ingredients listed in Appendix B.1 must comply with both Section 6 and Section 7.

7.3 Testable High-Risk Minor and Micro Inputs and Ingredients

7.3.1 All Affidavits must include the Project's definitions of Biotechnology and GMO as they appear in Appendix A.

7.3.2 Testable High-Risk Minor and Micro Inputs and Ingredients may demonstrate compliance based on Affidavits as long as these Inputs and Ingredients are the result of a system that has been designed to avoid GMOs. The suitability of systems designed to avoid GMOs is subject to review by the TA with the approval of the Project.

7.3.3 When available, valid certificates from third-party certifiers are acceptable alternatives to Affidavits under Section 7.3, if the third-party certification program satisfies the requirements for which an Affidavit would be used in Section 7.3.2.

7.3.3.a Except for honey and other derivatives of apiculture, Testable High-Risk Minor and Micro Inputs and Ingredients that are certified organic do not require an Affidavit.

7.4 Affidavit Compliance Based on Country of Origin[8]

7.4.1 Certain Testable and Non-Testable High-Risk crops and their derivatives that comprise a single Input may demonstrate compliance with aspects of the Standard based on country of origin.

7.4.2 The necessity or frequency of testing of certain Testable High-Risk crops and their single Input derivatives may be reduced by the TA based on an Affidavit.

7.4.3 The Affidavit must state that:

7.4.3.a Procurement procedures that require that the crop source or single Input derivative is grown strictly in specific countries are in place throughout the supply chain.

7.4.3.b No crop or crop-derivatives from outside those specific countries may be commingled.

7.4.3.c Procedures throughout the supply chain are in place for the segregation, cleanout, and traceability of compliant materials from non-compliant materials.

7.4.4 The Affidavits must be submitted to the TA for review prior to initial verification and, at minimum, updated and resubmitted annually upon each renewal.

7.4.5 The Project has issued standardized Affidavit templates for Section 7.4.3. These are the only Affidavits compliant with Section 7.4.

7.4.6 When available, valid third-party Identity Preservation (IP) certificates are acceptable alternatives to Affidavits when the scope of the third-party certification program satisfies the requirements for which an Affidavit would be used in Section 7.4.2.

7.5 Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients

7.5.1 Affidavits may be used to confirm the compliance of Monitored-Risk and Low-Risk Major, Minor, and Micro Inputs and Ingredients.

7.5.2 The Affidavit must attest to compliance with the requirement for classification as either Monitored Risk or Low Risk as described in Section 3.2, Table 3-1.

7.6 Non-Risk Major, Minor, and Micro Inputs and Ingredients

7.6.1 Affidavits may be used to confirm the compliance of Non-Risk Major, Minor, and Micro Inputs and Ingredients.

7.6.2 The Affidavit must attest to compliance with the requirement for classification as Non-Risk as described in Section 3.2, Table 3-1.

[8] The Project maintains the list of countries (and associated frequencies and necessities of testing) that comply with Section 7.4.2.

8 Livestock and Poultry

The following requirements are intended to complement other sections of the Standard. Where specific topics are addressed below (e.g., sampling, testing), these requirements are authoritative. Where special requirements are not given, requirements from elsewhere in the Standard apply.

Absence of all GMOs is the target for all Verified Products. Continuous improvement practices toward achieving this goal must be part of the Participant's quality assurance systems.

Livestock- and poultry-derived Products, Ingredients, and Inputs are High Risk because their Ration Inputs are within the scope of review and may be Testable or Non-Testable High Risk. These Products, Ingredients, and Inputs comply with the sampling and testing requirements of the Standard through the sampling and testing of Inputs to the animals' Rations and/or the seed used to grow the Inputs to the animals' Rations. Feed Inputs to Rations must be classified based on their Weight Percentage within the Ration, Risk Status, and Testability. Unless otherwise specified, compliance with the 5% Action Threshold is based on the quarterly average of all lots tested. In all cases, the animals cannot be GM; nor can they have been treated with or derived from Prohibited Substances listed under Section 2.2.3.

8.1 Compliance of Livestock- and Poultry-derived Products, Ingredients, and Inputs

Livestock- and poultry-derived Products, as well as livestock- and poultry-derived Ingredients and Inputs to Products, are considered High Risk and have different compliance pathways depending upon their Weight Percentage as present in the finished Product. Table 8-1 outlines the compliance requirements for livestock- and poultry-derived Products/Majors, Minors, and Micros when the livestock or poultry-derived material is or is present in the Product under evaluation. Table 8-1 is a summary; additional compliance requirements may apply.

Table 8-1 Compliance of Livestock- and Poultry-derived Products, Ingredients, and Inputs

Product/Major
1. Animals must comply with Section 8.2, Life Cycle. 2. Inputs to Rations are classified based on the combination of Weight Percentage as present in the Ration, Risk Status, and Testability. 3. Major Inputs to Rations are within the scope of review and must be found compliant with Table 8-2. 4. Major High-Risk Inputs to Rations must comply with: a. Section 4, Chain of Custody b. Section 8, Livestock and Poultry c. Section 8.8, Onsite Farm and Feed Mill Inspections 5. In addition to Ration compliance, the livestock or poultry-derived material must comply with: a. Section 4, Chain of Custody b. Section 5, Onsite Inspections c. Section 8.8, Onsite Farm and Feed Mill Inspections d. Section 10, Product Specifications and Labeling e. Section 11, Quality Assurance
Minor
1. Materials may comply with Standard requirements as a Product/Major. **OR** 2. Materials may comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients (e.g., Verified Status, organic certification).
Micro
1. Materials may comply with Standard requirements as either a Product/Major. **OR** 2. Materials may comply with Standard requirements as a Minor. **OR** 3. All Inputs to Rations are outside the scope of review; materials must comply with Section 3.1.3, Micro Inputs and Ingredients.

8.2 Life Cycle

Livestock- and poultry-derived Products, Ingredients, and Inputs must be from animals that comply with the following life-cycle feed guidelines.

8.2.1 Meat animals, including culls (other than poultry): starting at birth (the feed of nursing mothers is not evaluated) and ending at slaughter

8.2.2 Poultry, including spent hens: starting on the second day after hatching and ending at slaughter

8.2.3 Laying hens: starting 30 days prior to initial verification and for the remainder of the animal's productive life (including rest and molt periods)

8.2.4 Dairy animals: starting 30 days prior to initial verification and for the remainder of the animal's productive life (including dry periods)

8.2.5 Animals cannot be intentionally cycled on and off compliant feed. The use of non-compliant Major Inputs to the animals' Rations triggers a Major Non-conformity.

8.2.6 Removal of animals from a Non-GMO-compliant group (e.g., herd, flock) for medical treatment is permitted, during which time their feed is out of the scope of review, and no material (e.g., milk, eggs) may be collected from them for use in the Non-GMO supply chain. The animals must immediately resume Non-GMO-compliant feed once treatment is concluded and they are returned to the group.

8.3 Compliance of Feed Rations

The Weight Percentage of Inputs to Rations is calculated based on the weight of the Input as present in the Ration. Table 8-2 is a summary; additional compliance requirements may apply.

Table 8-2 Compliance of Inputs to Rations for Livestock- and Poultry-derived Products and Majors

Major	Minor	Micro
Testable High Risk		
1. Comply with Section 4, Chain of Custody, from the point of testing onward. 2. Operations must comply with Section 8.8, Onsite Farm and Feed Mill Inspections. **AND EITHER** a. Sampling and testing must comply with Section 8.4, Feed Sampling, Section 8.5, Testing Methodology, Section 8.6, Feed Compliance Through Compliant Seed, and Section 8.7, Feed Mills, as applicable. **OR** b. Where eligible comply with Section 7.4, Affidavit Compliance Based on Country of Origin.	1. Out of scope. **OR** 2. Comply as a Major. **OR** 3. Comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients.	1. Out of scope. **OR** 2. Comply as a Major. **OR** 3. Comply as a Minor. **OR** 3. Comply with Section 7.3, Testable High-Risk Minor and Micro Inputs and Ingredients.
Non-Testable High Risk		
1. Comply with Section 4, Chain of Custody, from the point of compliance with either Section 7.2, Non-Testable High-Risk Inputs and Ingredients or where eligible Section 7.4, Affidavit Compliance Based on Country of Origin, onward. 2. Operations must comply with Section 8.8, Onsite Farm and Feed Mill Inspections. **AND EITHER** a. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients. **OR** b. Where eligible comply with Section 7.4, Affidavit Compliance Based on Country of Origin.	1. Out of scope. **OR** 2. Comply as a Major. OR 3. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients.	1. Out of scope. **OR** 2. Comply as a Major. **OR** 3. Comply as a Minor. **OR** 4. Comply with Section 7.2, Non-Testable High-Risk Inputs and Ingredients.

8.3.1 Ration Reporting Requirements

8.3.1.a Dairy and laying operations must submit to the TA at initial verification a plan detailing the stages of life or production managed, including, at minimum, corresponding durations and Rations fed.

8.3.1.a.i Weight Percentage, Risk Status, and Testability attributes apply to all Ration Inputs as they appear within each individual Ration.

8.3.1.a.ii Multiple Rations that are materially different cannot be combined into a single Ration.

8.3.1.a.iii Multiple Rations spanning different stages of life or production cannot be combined into a single Ration unless they are materially homogeneous.

8.3.1.b Meat operations must submit to the TA at initial verification a plan detailing the stages of life or production, including, at minimum, corresponding durations and the Ration fed to the animals for the full length of their life cycle requirement as stated in Section 8.2.1.

8.3.1.c Poultry operations must submit to the TA at initial verification a plan detailing the stages of life or production, including, at minimum, corresponding durations and the Ration fed to the animals for the full length of their life cycle requirement as stated in Section 8.2.2.

8.3.1.d The option for Rations to demonstrate compliance on an as-fed basis will be revisited during the next Standard revision. Rations compliant on an as-fed basis are subject to additional reporting requirements, including, at minimum, the following:

8.3.1.d.i The corresponding dry-matter conversion of each individual Ration must accompany each as-fed Ration.

8.3.1.d.ii A written rationale for why compliance of Rations has been established on an as-fed basis.

8.3.1.e Rations compliant on a dry-matter basis have no additional reporting requirements.

8.4 Feed Sampling

Feed grown from commercially purchased seed and commercially purchased or produced feed must demonstrate compliance through the evaluation of, at minimum, the Major Inputs to the animals' Rations. Ongoing testing of Testable High-Risk Major Inputs is required.

8.4.1 Certified organic farming operations in which goods are pooled before final processing (e.g., dairy, ground meat, egg mixtures)

The sampling plan for certified organic operations must be based on testing a composite sample of the High-Risk feed Inputs from a representative selection of farms, with the intention of identifying and addressing any contamination

occurring in a Participant's operation. Farms are to be chosen based on the quarterly sampling density and selection requirements outlined in Table 8-3. Such sampling and testing must be representative of a Participant's operations in a Region.

8.4.1.a Regions

Regions must be designed such that farms within a Region are relatively similar and source their feed from the same or similar location(s). In order to inform the design of Regions, Participants must supply the TA with:

- Farm locations
- Feed mill locations
- List of feed mills serving each farm
- Processing facility locations
- Proposed Regions

This basic documentation must be accompanied by a global rationale for what factors are considered in creating the different Regions, how the consideration of these factors leads to variation within the Participant's operation being captured among Regions, and how farms within a Region are more alike than different.

8.4.1.b Quarterly Sampling Density and Selection

The number of farms within a Region determines the number of farms to be sampled. Fractions of farms are rounded up to the next whole number. Should a farm be chosen for sampling and testing and not have any Major High-Risk Inputs to sample and test onsite, another farm must be chosen at random from within that same Region.

Table 8-3 Quarterly Sampling Density and Selection

Number of Farms per Region	Number of Farms to be Sampled and Tested
Fewer than 10	Minimum of one farm tested per Region per quarter
10 to 20	Minimum of two farms tested per Region per quarter
21 to 50	10% of farms tested per Region per quarter
51 to 100	5% of farms tested per Region per quarter
Greater than 100	Minimum of six farms tested per Region per quarter

The sampling plan within each Region must include a random selection of farms each quarter. Annual sampling plans must be reviewed with the TA and may be adjusted over time to provide the most technically sound basis for continuous improvement.

Farms should retain a portion of each sample until test results come

back compliant in case re-testing is necessary or a sample tests above the Action Threshold and the Participant must seek the cause of contamination.

8.4.1.c Ration Reporting within the Regional Model

All farms in the Participant's supply chain must be prepared to supply full Rations to TAs. Full Ration reporting may include all Rations fed annually from every farm that is part of the Participant's operation or, at minimum, must include the full Rations from the previous quarter and any additional Major High-Risk Inputs to the current Rations, if not captured in the previous quarter's Rations, of each farm randomly selected for sampling and testing by the TA. The Major High-Risk Inputs to the Rations must be evaluated and found compliant.

8.4.1.d Testing within the Regional Model

Testing must comply with Section 6.3.3. Composite samples must be tested on a quarterly basis. When more than one test is needed, results may be averaged. Quarterly results or averages in excess of the Action Threshold will trigger an assessment of the cause of contamination and appropriate steps to eliminate identified sources of contamination.

Upon renewal, Participants must provide a report of any significant changes in the frequency of GMO presence in feed Inputs, the percentage of samples exceeding the Action Threshold, and steps taken to secure feed that tests at or below the Action Threshold.

8.4.2 Certified organic farming operations in which goods are not pooled (e.g., shell eggs, cut meat) and conventional farming operations

The sampling and testing plan for certified organic farming operations in which goods are not pooled and conventional farming operations may include either of the following:

8.4.2.a Sampling of every incoming lot of Testable High-Risk Major Input, testing each sample in compliance with Section 6.4 or Section 6.5 by each farmer in the Participant's operations, and quarterly averaging of results to comply with the Action Threshold

8.4.2.b Sampling of every incoming lot of Testable High-Risk Major Input, compositing of samples, and quarterly testing of composite samples by each farmer in the Participant's operations in compliance with Section 6.2.2

8.4.3 Group Compliance Model

Large certified organic farming operations where goods are pooled, large certified organic farming operations where goods are not pooled, and large conventional farming operations where goods are either pooled or not pooled, may demonstrate compliance with the Standard through a group compliance

model. The group compliance model must include an Internal Control System (ICS). All components of the ICS are subject to final approval by the TA. At a minimum, the ICS must include:

8.4.3.a A clearly defined scope outlining the ICS management structure, including personnel, titles, roles, contact information, and conflict of interest policy.

8.4.3.b A listing of farms, facilities, and/or operations within the group being overseen (i.e., group members), locations of all farms in the operation, locations of all feed mills, identification of which feed mills service which farms, locations of all processing facilities, locations where Parallel Processing is taking place, and the group member(s) responsible for testing.

8.4.3.c A training plan for ICS personnel, including how ICS personnel educate their group members.

8.4.3.c.i Each member of the group must have, and acknowledge access to, a copy of the most recent Standard version.

8.4.3.c.ii Each member of the group must have, and acknowledge access to, any relevant documents such as standard operating procedures (SOPs) and sampling and testing plans.

8.4.3.d A comprehensive plan for how each group member will comply with all relevant Standard sections based on the nature of their goods and Ration formulations, including Section 4, Section 8.2 through Section 8.8, Section 10, and Section 11.

8.4.3.d.i Frequency of inspection must be at least once per year by ICS personnel of all farms under the scope of the ICS.

8.4.3.d.ii Third-party inspections must be conducted annually on 10% of all conventional farms that are Parallel Processing the same Major High-Risk Inputs to Rations. Farms are chosen by the TA.

8.4.3.d.iii The comprehensive plan must include how the ICS will handle Minor Non-conformities.

8.4.3.d.iv The comprehensive plan must include how the ICS will handle Major Non-conformities.

8.4.3.e For large certified organic farming operations where goods are pooled, a sampling and testing plan in compliance with Section 8.4.1 and Section 8.6 is required for each group member responsible for testing.

8.4.3.f For large certified organic farming operations where goods are not pooled and for large conventional farming operations where goods are pooled or not pooled, a sampling and testing plan in compliance with Section 8.4.2 and Section 8.6 is required for each group member

responsible for testing.

8.4.3.g Documentation that outlines the frequency with which group members submit test results to the ICS.

8.4.3.h Documentation that outlines how the results will be handled (quarterly averaging) or pass-fail.

8.5 Testing Methodology

The testing method must yield valid results for all Testable High-Risk Inputs. Immunological testing methods may be used when compliant with Section 6.5. Molecular testing methods compliant with Section 6.4 must be used when immunological testing methods cannot be used and may be used in all cases in lieu of immunological testing methods.

8.6 Feed Compliance Through Compliant Seed

Under certain circumstances, compliance of livestock and poultry feed may be demonstrated based on use of compliant seed; in such cases post-harvest feed testing is not required. Neither seed compliant under Section 8.6.1, Section 8.6.2, or Section 8.6.3 nor feed derived from seed compliant under Section 8.6.1, Section 8.6.2, or Section 8.6.3 is eligible for verification.

8.6.1 **Farmer-saved seed and seed purchased from any neighboring farmer who does not have a retail seed operation** must be tested annually. Frequency of testing should increase if there are any changes that would significantly increase the likelihood of contamination. Testing may be conducted in compliance with either Section 6.4 or Section 6.5. If testing is conducted in compliance with Section 6.5, and the immunoassay is positive for any event, samples must be re-tested with molecular testing methods per Section 6.4 to demonstrate compliance with the 0.25% Action Threshold. If the sample tests above the Action Threshold, it cannot be planted.

8.6.2 **Freshly harvested and direct-fed forage, as well as silage and similarly fermented feed.** When post-harvest testing of freshly harvested and direct-fed forage and/or silage and similarly fermented feed is feasible, sampling must comply with Section 6.2, testing must comply with Section 6.3, and test results must comply with either Section 6.4 or Section 6.5. When post-harvest testing is not feasible because compliance cannot be established with one or more of the sections listed above, these feed Inputs may demonstrate compliance through seed testing, Affidavit, or use of Verified-Status seed. In all cases, the grower must demonstrate traceability from the planted field to the harvested feed crop.

8.6.2.a When test results are available, each lot of seed planted must be compliant with Section 6 and test at or below the Action Threshold.

8.6.2.b When test results are not available, each lot of seed planted must have a seed tag, an Affidavit from the seed supplier establishing that the seed is Non-GMO, an invoice, and an Affidavit from the grower confirming planting location.

8.6.2.c When Verified-Status seed is planted, each lot of seed must have the

seed supplier seed tag, an invoice, and an Affidavit from the grower confirming planting location.

8.6.3 **Alfalfa hay grown onsite and fed to resident animals** may demonstrate compliance by using Verified-Status seed, where each lot of seed is accompanied by a seed supplier seed tag, an invoice, and an Affidavit that includes confirmation of planting locations.

8.7 Feed Mills

8.7.1 Rations formulated by feed mills may be found compliant if:

8.7.1.a Every lot of Testable High-Risk Major Input to the Ration complies with Section 6.

8.7.1.b Every lot of Non-Testable High-Risk Major Input to the Ration complies with Section 7.

8.7.2 Or, feed sold by feed mills may be found compliant if:

8.7.2.a Every incoming lot of Testable High-Risk crop destined for the Non-GMO supply chain, regardless of future Weight Percentage in the on-farm Ration, complies with Section 6.

8.7.2.b Every incoming lot of Non-Testable High-Risk crop destined for the Non-GMO supply chain, regardless of future Weight Percentage in the on-farm Ration, complies with Section 7.

8.7.2.c The Non-GMO integrity of every Testable and Non-Testable High-Risk crop compliant with Section 8.7.2.a and Section 8.7.2.b is maintained through compliance with Section 4.

8.8 Onsite Farm and Feed Mill Inspections

8.8.1 All farms and feed mills may be subject to annual inspections at the discretion of the TA.

8.8.2 Unless the TA finds cause for inspection, inspections may not be required for:

8.8.2.a Certified organic farming operations in which goods are pooled or not pooled during final processing

8.8.2.b Conventional farming operations that are not Parallel Processing the same Major High-Risk Input to a Ration

8.8.2.c Feed mills that are not Participants

8.8.3 At the TA's discretion, unannounced inspections may be used to ensure compliance with the Standard.

8.8.4 Notwithstanding any of the above, large conventional farming operations compliant with Section 8.4.3 are required to have 10% of all farms that are Parallel Processing the same Major High-Risk Inputs to Rations inspected by a third party on an annual basis. Farms will be chosen by the TA.

9 Special Requirements for Specific Products, Ingredients, and Inputs

The following requirements are intended to complement other sections of the Standard. Where specific topics are addressed below (e.g., sampling, testing), these requirements are authoritative. Where special requirements are not given, requirements from elsewhere in the Standard apply.

9.1 Apiculture

Honey and other goods derived from apiculture must meet the following requirements:

9.1.1 The bees' forage area (defined as the area within a 4-mile radius of the hives) must be sufficiently free of GM commercial agriculture.

9.1.2 Any supplemental bee feed must be evaluated for compliance with Section 3.

9.1.3 Certified organic honey and other Inputs or Ingredients derived from certified organic apiculture may be deemed compliant with the Standard based on a signed Affidavit from the organic certifier. The Affidavit must:

9.1.3.a Meet all requirements of Section 7.

9.1.3.b Attest that the organic certifier has confirmed that the apiary is adhering to the Organic Apiculture Standard as formally recommended by the National Organic Standards Board (NOSB) to the National Organic Program (NOP).[9]

9.2 Beer, Wine, and Liquor

9.2.1 Fermentation Microorganisms used in the production of beer, wine, and liquor Products, Ingredients, and Inputs are not considered Processing Aids under the Standard, are ineligible for Section 3.1.3.b, and must be Non-GMO.

9.2.2 Processing Aids used in the production of beer, wine, and liquor are subject to the compliance requirements in Section 2.2.2.

9.2.3 Inputs to the fermentation media for beer, wine, and liquor Products, Ingredients, and Inputs are classified according to their Weight Percentage as represented in the finished Product, Risk Status, and Testability and must be compliant with the appropriate compliance pathways.

9.2.4 Beer, wine, and liquor Products will be held to the same level of evaluation as Products with Ingredient panels.

9.3 Microorganisms

9.3.1 When Microorganisms or Inputs or Ingredients derived from Microorganisms are Products or Major or Minor Ingredients, both the Microorganism and the Growth Media are within the scope of review and must be compliant.

[9] NOSB. 2010. Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), Subject: Apiculture Recommendation. October 28, 2010.

9.3.1.a A standardized Non-Testable High-Risk Affidavit in compliance with Section 7.2 is required.

9.3.2 Inputs to Growth Media must be categorized into Major, Minor, and Micro Ingredients based on their representative Weight Percentage in the finished Product and be compliant according to the appropriate compliance pathways.

9.3.3 When Microorganisms or Inputs or Ingredients derived from Microorganisms are Micro Ingredients, the Microorganism is within the scope of review, but the Growth Media are not.

9.3.3.a A standardized Non-Testable High-Risk Affidavit in compliance with Section 7.2 is required and must be supplied to the TA at initial verification. Updated standardized Non-Testable High-Risk Affidavits must be resubmitted to the TA no later than by the third annual renewal and every 3 years thereafter.

9.4 Probiotics

9.4.1 When probiotic Microorganisms or Inputs or Ingredients derived from probiotic Microorganisms are Products, Major, Minor, or Micro Ingredients, the probiotic Microorganism is within the scope of review and must be compliant. The Growth Media for probiotic Microorganisms as Inputs, Ingredients, and Products are temporarily outside the scope of evaluation. The availability of this exemption will be revisited during the next Standard revision.

9.4.1.a A standardized Non-Testable High-Risk Affidavit in compliance with Section 7.2 is required.

9.5 Seafood

Section 9.5 applies to all saltwater and freshwater aquatic animals.

9.5.1 Farm-raised seafood (in captivity from egg to harvest and/or where nutrient additions are provided) will be fully evaluated as a High-Risk Product, Ingredient, or Input and will require the evaluation and compliance of Ration Inputs.

9.5.2 Products, Ingredients, and Inputs derived from farm-raised seafood will be evaluated in the same manner as livestock and poultry Products, Ingredients, and Inputs in Section 3 and Section 8.

9.5.3 The feed of seafood may be compliant under Section 7.5 if the Affidavit establishes that the organism was caught in the wild.

9.6 Vitamins and Supplements

9.6.1 The Growth Media for Microorganisms from which Enzyme Inputs and Ingredients to vitamin and supplement Products are derived, are temporarily outside of the scope of evaluation. The availability of this exemption will be revisited during the next Standard revision.

10 Product Specifications and Labeling

10.1 Specifications for Obtaining Inputs and Ingredients

10.1.1 Major and Minor Inputs and Ingredients must be sourced from Non-GMO sources. Micro Inputs and Ingredients should be sourced from Non-GMO sources.

10.1.2 For Products verified under the PVP, Participants cannot knowingly plant, purchase, or use Inputs or Ingredients that are not compliant with the Standard.

10.1.3 The written specifications for all Products, Ingredients, and Inputs must include requirements regarding Standard compliance and must be updated if the Participant changes suppliers, Inputs, or Ingredients.

10.1.4 When spot purchasing is necessary, unverified Inputs and Ingredients should be avoided; Participants must seek out Verified-Status Inputs and Ingredients of appropriate scope. If a spot purchase of unverified Input or Ingredient is made, the Participant must:

10.1.4.a Justify to the TA why a Verified-Status Input or Ingredient was not used

10.1.4.b Provide evidence that any Testable High-Risk Input or Ingredient that is spot purchased has been tested in accordance with the requirements of the Standard and that the test results are at or below the relevant Action Threshold

10.1.4.c Demonstrate that all Non-Testable High-Risk Inputs or Ingredients that are spot purchased are compliant with all applicable requirements of Table 3-3

10.1.4.d Demonstrate that all Verified-Status Inputs or Ingredients or Low-Risk Inputs or Ingredients that are spot purchased are compliant with all applicable requirements of Table 3-2

10.1.4.e Provide the TA with documentation of the purchase, including Affidavits, sampling information, and test results. This reporting must be done in a timely manner.

10.1.5 Constraints on spot purchasing may be enforced at the discretion of the TA. For example, repeated spot purchases from the same supplier could be grounds for this allowance to be revoked or restricted.

10.2 Labeling

10.2.1 Wholesale and retail Products must comply with the labeling requirements outlined in the Standard.

10.2.2 The TA will review labels to assess compliance with these claim guidelines.

10.2.3 **Labeling claims must be accurate, truthful,** and not mislead the consumer about the GMO content of the Product. Any reference to the Non-GMO Project or use of the verification mark must be approved by a written agreement with the

Project. One-hundred percent GMO absence claims are not acceptable and include, but are not limited to, “contains zero GMOs,” “GMO-free,” and “GE-free.” No other non-GMO certifications may be used in conjunction with the Non-GMO Project verification mark.

10.2.4 High-Risk Micro Ingredients other than artificial and natural flavors, Enzymes, and Microorganisms that have been Micro exempted under Section 3.1.3.b cannot be listed with the same name, or any other common name, on the PDP of a retail consumer Product.

10.2.5 Ingredients other than artificial and natural flavors, Enzymes, and Microorganisms cannot be named on the PDP of a retail consumer Product if one or more of their sub-Ingredients (as they appear in a parenthetical Ingredient declaration or supplement facts panel) have been Micro exempted under Section 3.1.3.b and the Micro-exempted sub-Ingredient(s) is/are considered to reasonably characterize the Ingredient appearing on the PDP.

11 Quality Assurance

11.1 Total Quality Management Systems

11.1.1 The Participant’s quality assurance and quality control program, including SOPs, forms, and documents, must be revised as needed to ensure compliance with the Standard, and revisions must be documented.

11.1.2 Compliance with applicable requirements of the Standard must be identified as key quality indicators of the Participant’s total quality system.

11.1.3 The Participant must monitor and control the compliance of Inputs and Ingredients purchased and finished Products, and this must be documented.

11.1.4 Where needed, additional training must be provided to relevant staff to ensure that SOPs in support of Standard compliance are followed, and training must be documented.

11.1.5 All SOPs, documents, forms, and specifications needed by personnel to fulfill the requirements of the Standard must be readily available to relevant personnel.

11.1.6 Records must be retained for a minimum of 3 years.

11.2 Non-conformities and Corrective and Preventive Actions

11.2.1 Global Non-conformity and Corrective and Preventive Action Requirements

11.2.1.a Full compliance with the Standard must be achieved prior to initial verification.

11.2.1.b Changes in processes, procedures, Inputs, Ingredients, or Products, that could impact compliance with any aspect of the Standard, will be deemed Non-conformities and will trigger corrective and preventive actions.

11.2.1.c Non-conformities discovered during the renewal process must be addressed in order to maintain verification.

11.2.1.d Mid-term Non-conformities discovered through internal quality assurance processes, complaints from customers, third-party surveillance, or third-party audits, will require corrective and preventive action as described in Section 11.2.2 or in Section 11.2.3 as appropriate.

11.2.1.e Identification of Non-conformities, corrective and preventive actions, root cause analyses, and successful remediation of the Non-conformity must be documented.

11.2.1.f All documentation associated with ongoing application of approved corrective and preventive actions must be made available to the TA upon request.

11.2.2 Major Non-conformities

Major Non-conformities must be reviewed at the time of occurrence, documented, and immediately reported in writing to the TA by the Participant.

11.2.2.a Discovery of any Major Non-conformity must be followed by a timely root-cause analysis and corrective and preventive action plan. “Timely” is typically considered to be within 7 days and rarely longer than 30 days.

11.2.2.b Corrective and preventive action plans must include the identification of persons responsible for their execution, defined timelines for actions, and the desired results.

11.2.2.c Findings of the root-cause analysis must be reported in writing to the TA, together with the planned corrective and preventive actions to be undertaken.

11.2.2.d The TA will review, and at their discretion, approve the findings of the root-cause analysis and the planned corrective and preventive actions.

11.2.2.e Corrective and preventive actions must be completed in a timely manner, typically within 30 days and rarely longer than 90 days after the completion of the root-cause analysis and corrective and preventive action plan. Documentary evidence must be submitted to the TA within 5 days of the completion of corrective and preventive actions. The TA will review and, at their discretion, approve all corrective and preventive action evidence.

11.2.2.f Any delays in the timeline from reporting to completion of corrective and preventive actions must be justified in writing and approved by the TA.

11.2.2.g Any known Major Non-conformity that goes unreported or uncorrected or keeps recurring according to the requirements in Section 11.2.2 will

be cause for the Product or the Participant to be removed from the PVP.

11.2.2.h Repeated non-conformance with the Action Threshold may require mid-term re-evaluation of the Product.

11.2.3 Minor Non-conformities

11.2.3.a Minor Non-conformities will trigger corrective and preventive actions.

11.2.3.b Minor Non-conformities and corrective and preventive actions must be reviewed, at minimum, at the time of renewal.

11.2.3.c Renewal will be contingent upon appropriate resolution of any such Minor Non-conformity.

11.3 Renewal

11.3.1 Renewal evaluation of every Verified Product will be required at least annually.

11.3.2 Renewal evaluation must ensure that, at minimum:

11.3.2.a The Product and all Ingredients and Inputs within the scope of review are compliant under the current Standard version.

11.3.2.b All evidence of compliance on file with the TA is current and active.

11.3.2.c All Non-conformities have been addressed.

11.3.3 No changes to the Product or its manufacture or processing that would compromise the Product's compliance with the Standard have occurred.

11.3.4 The Product is compliant with any applicable Standard revisions.

The TA may require a Participant to submit updates more frequently if history shows a pattern of Major Non-conformities occurring as a result of unannounced changes to the operation. Such changes include, but are not limited to, the following: changes in Product composition that involve High-Risk Inputs or Ingredients; changes in suppliers of High-Risk Inputs or Ingredients; changes in processes or procedures that alter the segregation, cleanout, or traceability of Inputs, Ingredients, or Products; or changes in specifications of High-Risk Inputs, Ingredients, or of a final Product that contains High-Risk Inputs or Ingredients.

Appendix A –Terms and Definitions

Affidavit – A formal document either created and supplied by the Project or TA, or provided by a Participant, that includes a written and signed statement confirming specific characteristics of a given organism, crop, precursor, Input, Ingredient, system, process, or operation.

Biotechnology[10] – the application of:

a. in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or
b. fusion of cells beyond the taxonomic family, that overcame natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection.

Certificate of Approval – An annually renewed document confirming a laboratory's compliance with, and participation in, the Non-GMO Project Approved Laboratory Program. It includes the list of High-Risk crops for which the laboratory is approved to test.

Certificate of Verification (COV) – An annually renewed document demonstrating compliance with the PVP which includes a signed written agreement with the Project, a signed written agreement with the TA (where applicable), and Product-level compliance with the Standard.

Compost – Decayed organic material used as a fertility amendment in agricultural production that is produced by a combination of actions over time by Microorganisms, invertebrates, temperature, and other elemental factors (e.g., moisture content, aeration). Composted material shows practically no macroscopic indication as to the original substrate(s) from which it was made.

Enzyme – A protein molecule produced by a living organism that acts as a catalyst to bring about a specific biochemical reaction.

Functional Enzyme – An Enzyme that has not been denatured (e.g., by being subjected to high heat, harsh acids or bases, ultrafiltration, or centrifugation) and thus retains its catalytic functioning capability.

Genetically Engineered or Genetic Engineering (GE) – See Genetically Modified or Genetic Modification.

Genetically Modified or Genetic Modification (GM) – A term referring to the result of the application of Biotechnology.[11]

Genetically Modified Organism (GMO) – An organism to which Biotechnology[12] has been applied and derivatives of such an organism; cloned animals are included within this definition.

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[10] Adapted from Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity.

[11] As defined in Appendix A – Terms and Definitions.

[12] As defined in Appendix A – Terms and Definitions.

Growth Media – Materials or mixtures of materials designed to support the growth of Microorganisms.

High Risk – Organisms and the Inputs and Ingredients derived from them for which GM counterparts are widely commercially available.

Ingredient – Any material or substance that is a component in the creation of a wholesale or retail consumer good and present in said good in either its original or altered form.

Input – Any material or substance that is used in the production of a wholesale or retail consumer good. Not all Inputs are necessarily represented in, or present in, said good.

Internal Control System (ICS) – A robust internal oversight structure that functions as the administrative body responsible for maintaining compliance of all members with one or more set(s) of requirements.

Low Risk – Organisms and the Inputs and Ingredients derived from them that are not classified as Monitored Risk or High Risk.

Major Non-conformity – A deviation that could affect the compliance of an Input or Ingredient with the relevant Action Threshold, such as unintentional contamination of the Ingredient with GM material, or that could impact the compliance of an Input or Ingredient with Section 7.2.

Matrix – All sample constituents other than the analyte of interest. This encompasses the composition of the sample (single or multi Ingredient) and the state of processing (raw grain vs. flour).

Microorganism – A microscopic organism (such as a bacterium, yeast, fungus, or alga).

Minor Non-conformity – A deviation that could not cause any of the relevant Inputs or Ingredients to the Product to exceed the relevant Action Threshold. This includes immaterial changes to procedures, recordkeeping, documentation, or anything else immaterial that does not have the potential to impact compliance with the relevant Action Threshold.

Monitored Risk – Organisms and the Inputs and Ingredients derived from them for which GM counterparts are in the research and development stages, which have been developed but are not widely commercially available, or for which known GM contamination has occurred.

Must – A mandatory requirement under the Standard.

Non-conformity – Any deviation in operations that has not been approved by the TA.

Non-GMO or Non-GM – An organism to which Biotechnology[13] has not been applied and derivatives of such an organism.

Non-Risk – Inputs and Ingredients that are not derived from biological organisms and are not, therefore, susceptible to Genetic Modification.

Non-Risk Category – A group of one or more types of wholesale or retail goods whose formulations involve no Inputs or Ingredients of biological origin.

[13] As defined in Appendix A – Terms and Definitions.

Non-Testable – Not having any precursor at any point in the supply chain for which current testing methodologies can distinguish between the Non-GM and GM versions or where publicly commercially available tests do not exist.

Parallel Processing – The practice of using the same facility for handling both Project-compliant and non-compliant Inputs, Ingredients, and/or Products.

Participant – A company that is seeking verification within the PVP and signs a License Agreement with the Project.

Principal Display Panel (PDP)[14] – Portion of the package label that is most likely to be seen by the consumer at the time of purchase (often the front face of the packaging).

Processing Aid[15] – (a) Substances [Inputs] that are added to a food [Product or Ingredient] during the processing of such food but are removed in some manner from the food before it is packaged in its finished form. (b) Substances [Inputs] that are added to a food [Product or Ingredient] during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food. (c) Substances [Inputs] that are added to a food [Product or Ingredient] for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

Producing Facility – Location where Inputs and Ingredients are combined to create the finished Product and/or where bulk Product is packaged for final sale and/or where bulk Product is labeled for final sale.

Product – A unique branded formula and process, where process could be either the manufacturing or facility process. "Product" refers to goods enrolled in the PVP.

Program Documents – The Non-GMO Project Standard, The Non-GMO Project Program Rules and Procedures, The Non-GMO Project Trademark License and Program Participation Agreement, and The Non-GMO Project Trademark Use Guide.

Ration – The feedstuffs offered to an animal during a 24-hour period.

Region – A geographic area with relatively homogeneous farm operations and sources of livestock or poultry feed, typically encompassing one or more states, in which farms ship unprocessed livestock or poultry materials to one or a few processors.

Risk Status – The attribute assigned to a material that denotes the likelihood that a material is or is derived from a GMO.

Should or May – A non-mandatory recommendation or recommended practice.

Standard – The Standard for the Non-GMO Project Product Verification Program, which is this document.

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[14] U.S. Department of Health and Human Services. 2013. A Food Labeling Guide, Guidance for Industry. January, 2013.

[15] 21 CFR § 101.100 (2018).

Supplier – Any party from whom an Input and/or Ingredient is obtained.

Synthetic Biology – The development of novel, artificial nucleic acid sequences, biological pathways, organisms, or devices or the redesign of existing natural biological systems.

Technical Administrator (TA) – A certification body approved by the Project to assess compliance with the Standard on behalf of the Project.

Testable – Having one or more precursors at at least one point in the supply chain for which current testing methodologies can distinguish between the Non-GM and GM versions and where publicly commercially available tests exist.

Verified – A finished Product's status when the TA establishes that the Product is compliant with all applicable requirements of the Standard and has satisfied all other elements of the Product Verification Program. Verified refers to the Product Verification Program as a whole, as opposed to particular requirements.

Verified Status – Products that have been Verified under the PVP at wholesale or retail and are purchased for use as Inputs or Ingredients to different Products enrolled in the PVP.

Viable Microorganism – A microscopic organism (such as a bacterium, yeast, fungus, or alga) that performs metabolic functions and reproduces/multiplies.

Weight Percentage –The percentage by weight of a material as present in, or represented in, a finished Product after the removal of salt, added water, qualifying Processing Aids, and purified CO_2.

Appendix B – High-Risk List

Organisms, and Products, Ingredients, and Inputs derived from organisms, for which GM versions are widely commercially available; this includes certain crops, their derivatives, and animal-derived materials.

B.1 Testable and Non-Testable High-Risk Inputs and Ingredients

B.1.1 Crops

The following list of Testable and Non-Testable High-Risk crops is exhaustive:

	Testable	Non-Testable
• Alfalfa	✓	
• Apple		✓
• Canola[16]	✓	✓
• Corn (except popcorn)	✓	
• Cotton	✓	
• Eggplant		✓
• Papaya	✓	
• Pineapple		✓
• Potato		✓
• Soy[16]	✓	✓
• Sugar beets	✓	
• Zucchini and yellow summer squash	✓	

[16] Note that this crop is both Testable and Non-Testable and must therefore be compliant with the requirements in both Section 6 and Section 7.

B.1.2 Animal-derived Inputs and Ingredients[17]

	Testable	Non-Testable
• Meat, dairy, eggs, wool, hides, honey, seafood, and any other materials or substances originating from animals	✓	✓
• Livestock and poultry feed[18]	✓	✓
• Bee forage and feed	✓	✓
• Fish and other aquatic animal feed	✓	✓

B.1.3 Microorganism and Enzyme Inputs and Ingredients

	Testable	Non-Testable[19]
• Algae		✓
• Bacteria		✓
• Enzymes		✓
• Microbial cultures and starters		✓
• Yeast		✓

B.1.4 Ingredients or Substances with Synthetic Biology Counterparts

	Testable	Non-Testable
		✓

Examples of Inputs and Ingredients that could be derived from the High-Risk organisms in Appendix B can be found in the publication High-Risk Inputs: Examples. Inputs and Ingredients that could be derived from High-Risk organisms are High Risk under the Standard and must be sourced Non-GMO where required.

[17] Animal-derived Products, Ingredients, and Inputs are High-Risk because their feed Inputs are within the scope of review and may be Testable or Non-Testable High-Risk.

[18] Per Section 8, Section 9.1, and Section 9.5, verification of livestock and poultry, bee, and seafood Products and Major Inputs and Ingredients requires the testing of feed.

[19] Note that Non-Testable Inputs and Ingredients must be compliant with Section 7.

Appendix C –Monitored-Risk List

Organisms, and Products, Ingredients, and Inputs derived from those organisms, for which GM counterparts are in the research and development stages, which have been developed but are not widely commercially available, or for which known GMO contamination has occurred.

C.1 Testable and Non-Testable Monitored-Risk Inputs and Ingredients

C.1.1 Crops

	Testable	Non-Testable
• Alfalfa		✓
• Banana		✓
• *Beta vulgaris,*(e.g., chard, table beets) – cross pollination risk from GM sugar beets	✓	
• *Brassica napus* (e.g., rutabaga, Siberian kale) – cross pollination risk from GM canola	✓	
• *Brassica rapa* (e.g., bok choy, mizuna, Chinese cabbage, turnip, rapini, tatsoi) – cross pollination risk from GM canola	✓	
• Camelina (false flax)		✓
• *Cucurbita pepo* (e.g., acorn squash, delicata squash, patty pan squash, pumpkin, and spaghetti squash) – cross-pollination risk from GM squash	✓	
• Flax	✓	✓
• Hemp		✓
• Lettuce		✓
• Mushroom		✓
• Mustard	✓	
• Oats		✓
• Orange		✓
• Peanuts		✓
• Peas		✓
• Rice	✓	✓
• Sugarcane		✓
• Tomato		✓
• Wheat	✓	✓

Summary of Changes from Version 16 of the Standard (Hyperlinked)

Summary of Changes (SoC) from v16 to v16.1 Published March 31, 2023

The table below identifies changes made from Version 16 (v16) to Version 16.1 (v16.1) of the Standard. The left column provides links to the location of the revised text in v16.1 by section number. Titles are included only for Level 1 headers. When changes were made to a specific row in a table, further details are provided. Sections identified in the left column that were not retained in v16 have no links. Text that appears in orange (orange) in the right column identifies the specific additions made to the text. Text that has been struck (~~struck~~) identifies specific deletions made to the text.

Example		
Original Text	**Change**	**Current Version Text**
The Non-GMO Project has published 18 standard versions since 2007.	The Non-GMO Project has published ~~18~~20 standard versions since 2007.	The Non-GMO Project has published 20 standard versions since 2007.

This table is not the Standard and should not be used to evaluate Products, Ingredients, or Inputs for verification. Should text in the column titled "Change" not match text published in v16 exactly, text published in v16.1 always takes precedence.

Standard v16.1 Section	Change
1, Introduction	The Introduction of the Standard describes the structure of the PVP as a way to provide context to readers. Since v16 was published, one new Program Document has been created and another has been made publicly available on the Project's website. The body of the Introduction was updated by listing each individual Program Document, introducing the concept of "Program Documents," and adding the requirement that Participants must comply with all Program Documents to attain verification: In support of our mission, the Non-GMO Project offers a Product Verification Program (PVP) whereby Participants may enroll wholesale goods and retail consumer goods as Products for evaluation against, and determination of compliance with, the Non-GMO Project Standard. The PVP also includes the Non-GMO Project Program Rules and Procedures, the Non-GMO Project Trademark Use Guide, and a written agreement between the Participant and the Non-GMO Project, collectively referred to as Program Documents.~~, and w~~Where applicable, a written agreement between the Participant and one or more Technical Administrators (TAs) is also required. If all elements of the PVP are satisfied, including

<table>
<tr><th>Standard v16.1 Section</th><th>Change</th></tr>
<tr><td></td><td>meeting the compliance requirements set forth by the Non-GMO Project Standard, goods may attain Non-GMO Project verification.

To monitor compliance with the PVP, the Non-GMO Project maintains surveillance and auditing programs. The surveillance program routinely tests Verified Products and Inputs and Ingredients to same, for compliance with the Action Thresholds outlined in the Non-GMO Project Standard. The auditing program is in place to ensure that the appropriate supporting documentation associated with Verified Products is on file and fulfills the requirements of the PVP.

Compliance with all Program Documents listed in Table 1-1 is required to attain Non-GMO Project Verification.</td></tr>
<tr><td>Table 1-1</td><td>Table 1-1 was added to complement the requirement that all Participants must comply with Program Documents to attain verification and to streamline access to publicly available Program Documents. Each Program Document is listed with its official title and a hyperlink to the most recent version:

Table 1-1 Product Verification Program Documents
<table><tr><th>Product Verification Program Documents:
https://www.nongmoproject.org/product-verification-resources/</th></tr><tr><td>The Non-GMO Project Standard

The Non-GMO Project Program Rules and Procedures

The Non-GMO Project Trademark Use Guide

The Non-GMO Project Trademark License and Program Participation Agreement</td></tr></table>The Non-GMO Project Standard Version 16.1 March 31, 2023</td></tr>
<tr><td>v16 Section 2.1.2.b</td><td>The requirement that goods be sold in either the U.S. or Canada to be eligible for Non-GMO Project Verification was struck from the Standard. Sales territories as they relate to eligibility for verification, along with use of the Non-GMO Project verification mark, are now covered in other Program Documents such as The Non-GMO Project Program Rules and Procedures, The Non-GMO Project Trademark License and Program Participation Agreement, and The Non-GMO Project Trademark Use Guide:

2.1.2 The following types of goods are ineligible for verification:</td></tr>
</table>

Standard v16.1 Section	Change
	2.1.2.a Controlled substances under U.S. or Canadian law and all other prohibited Inputs and Ingredients listed under Section 2.2.3 ~~**2.1.2.b** Goods that are not sold in the U.S. or Canada~~ **2.1.2.~~c~~b** Certain medicines and other medical goods **2.1.2.~~d~~c** Live animals **2.1.2.~~e~~d** Synthetic pesticides **2.1.2.~~f~~e** Goods composed entirely of Non-Risk Inputs and Ingredients and that are part of a Non-Risk Category **2.1.2.~~f~~e.i** Non-Risk Categories include, but are not limited to, 100% salt goods, unflavored still beverages, unflavored carbonated beverages, and unflavored electrolyte beverages **2.1.2.~~g~~f** Goods making a voluntary or mandatory disclosure under The National Bioengineered Food Disclosure Standard[1] Footnote 1: 7 CFR § 66 (2018).
2.2.3.e	Language was added to clarify the prohibition on Synthetic Biology: **2.2.3.e** Synthetic Biology,[3] ~~and~~ its derivatives, and any organisms, Inputs, or Ingredients, or derivatives thereof, represented as synthetic biology[3] in any public communications[4] Footnote 3: The terms "Synthetic Biology" (uppercase and defined in Appendix A) and "synthetic biology" (lowercase) are referenced intentionally here. As there is no universally accepted definition for synthetic biology, the term "synthetic biology" (lowercase) includes usage of that term (and comparable terms) by industry even if such terms are not necessarily in full alignment with the Standard's definition. Footnote 4: Public communications include, but are not limited to, marketing materials, patent filings, SEC filings and other regulatory documents.

Standard v16.1 Section	Change
3.1.3.a.i, 3.1.3.a.ii, Footnote 5, and Footnote 6	The statement that compliance with Sections 3.1.3.a.i and 3.1.3.a.ii is required by January 1, 2022 was struck from the Standard. Compliance with Sections 3.1.3.a.i and 3.1.3.a.ii is now required of all new and existing Products given that the publication date of v16.1 is well past January 1, 2022: **3.1.3.a Inputs and Ingredients ineligible for Micro Exemption**: **3.1.3.a.i High-Risk Ingredients on the List of Bioengineered Foods.**~~3~~[5] ~~Compliance with Section 3.1.3.a.i is required by January 1, 2022.~~ **3.1.3.a.ii High-Risk Ingredients not on the List of Bioengineered Foods**[~~4~~6]for which the Participant has actual knowledge that the Ingredients contain detectable modified genetic material, and said Ingredients retain detectable modified genetic material in the finished Product.~~ Compliance with Section 3.1.3.a.ii is required by January 1, 2022.~~ Footnote ~~3~~5: 7 CFR § 66.1 (2018); 7 CFR § 66.6 (2018). Footnote ~~4~~6: 7 CFR § 66.6 (2018).
6.5.2	The requirement that analysts using immunological methods to demonstrate compliance with the Standard be competent was clarified by adding that they must also be capable of interpreting the results of the tests that they are conducting: **6.5.2 Analysts must be trained, and their proficiency established** to ensure that they use and interpret the tests reliably and according to the manufacturer's specifications. Participants must document the in-house training and evaluation of performance.
6.5.3.a.i and 6.5.3.a.ii	The requirements for compliant quantitative immunological methods were updated to reflect emerging technologies impacting the GMO landscape: **6.5.3.a** Quantitative immunological methods may be used to demonstrate compliance with the Action Threshold when: **6.5.3.a.i** The result for each assay counted toward overall contamination is either below the limit of detection or returns a number within the range of quantification and is not above the upper limit of the range of detection.

Standard v16.1 Section	Change
	6.5.3.a.ii The overall contamination of the~~sum of each test panel for the~~ Testable High-Risk precursor, Input, or Ingredient is indicated by the sum of each test panel or by following the manufacturer's instructions for the interpretation of test panel results.~~at or below the relevant Action Threshold.~~
Footnote 7	Version 16 Footnote 5 was renumbered to v16.1 Footnote 7
Footnote 8	Version 16 Footnote 6 was renumbered to v16.1 Footnote 8
Footnote 9	Version 16 Footnote 7 was renumbered to v16.1 Footnote 9
Footnote 10	Version 16 Footnote 8 was renumbered to v16.1 Footnote 10
Footnote 11	Version 16 Footnote 9 was renumbered to v16.1 Footnote 11
Footnote 12	Version 16 Footnote 10 was renumbered to v16.1 Footnote 12
Footnote 13	Version 16 Footnote 11 was renumbered to v16.1 Footnote 13
Footnote 14	Version 16 Footnote 12 was renumbered to v16.1 Footnote 14
Footnote 15	Version 16 Footnote 13 was renumbered to v16.1 Footnote 15
Appendix A – Terms and Definitions: Program Documents	The term "Program Documents" was defined in Appendix A – Terms and Definitions to complement the addition of the term and the requirement that Participants comply with all Program Documents to attain verification to the body of v16.1 Section 1, Introduction: **Program Documents** – The Non-GMO Project Standard, The Non-GMO Project Program Rules and Procedures, The Non-GMO Project Trademark License and Program Participation Agreement, and The Non-GMO Project Trademark Use Guide.
Appendix B.1.1, v16 Footnote 14, Footnote 16	Language regarding compliance timelines for the Non-Testable High-Risk Crops "Apple," "Eggplant," and "Pineapple," was updated to reflect the new publication date of v16.1. The statement "Beginning January 1, 2022[14]" with v16 Footnote 14 that existed at the intersection of rows containing "Apple," "Eggplant," and "Pineapple," and the column containing "Non-Testable" was replaced with a checkmark (✓) and the accompanying v16 Footnote 14, deleted. In addition, v16 Footnote 15 was renumbered to v16.1 Footnote 16:

<table>
<tr><th>Standard v16.1 Section</th><th>Change</th></tr>
<tr><td></td><td>
B.1.1 Crops
The following list of Testable and Non-Testable High-Risk crops is exhaustive:
<table>
<tr><th></th><th>Testable</th><th>Non-Testable</th></tr>
<tr><td>• Alfalfa</td><td>✓</td><td></td></tr>
<tr><td>• Apple</td><td></td><td><s>Beginning January 1, 2022[14]</s>✓</td></tr>
<tr><td>• Canola<s>[15]</s>[16]</td><td>✓</td><td>✓</td></tr>
<tr><td>• Corn (except popcorn)</td><td>✓</td><td></td></tr>
<tr><td>• Cotton</td><td>✓</td><td></td></tr>
<tr><td>• Eggplant</td><td></td><td><s>Beginning January 1, 2022[14]</s>✓</td></tr>
<tr><td>• Papaya</td><td>✓</td><td></td></tr>
<tr><td>• Pineapple</td><td></td><td><s>Beginning January 1, 2022[14]</s>✓</td></tr>
<tr><td>• Potato</td><td></td><td>✓</td></tr>
<tr><td>• Soy<s>[15]</s>[16]</td><td>✓</td><td>✓</td></tr>
<tr><td>• Sugar beets</td><td>✓</td><td></td></tr>
<tr><td>• Zucchini and yellow summer squash</td><td>✓</td><td></td></tr>
</table>

<s>Footnote 14: Beginning January 1, 2022, Apple, Eggplant, and Pineapple and their derivatives must be compliant as Non-Testable High-Risk crops.</s>

Footnote <s>15</s>16: Note that this crop is both Testable and Non-Testable and must therefore be compliant with the requirements in both Section 6 and Section 7.
</td></tr>
<tr><td>Footnote 17</td><td>Version 16 Footnote 16 was renumbered to v16.1 Footnote 17</td></tr>
<tr><td>Footnote 18</td><td>Version 16 Footnote 17 was renumbered to v16.1 Footnote 18</td></tr>
<tr><td>Footnote 19</td><td>Version 16 Footnote 18 was renumbered to v16.1 Footnote 19</td></tr>
</table>